

September 4, 2002

Ms. Sandra Titus Center for Drug Evaluation and Research (HFD-21) U.S. Food and Drug Administration 5600 Fishers Lane, Room 1093 Rockville, Maryland 20857

Dear Ms. Titus:

The August 20, 2002, *Federal Register* contained an announcement of the September meeting of the U.S. Food and Drug Administration's Nonprescription Drugs Advisory Committee (NDAC). The meeting agenda includes discussions that may affect the future of certain over-the-counter pain (OTC) medications. Therefore, I am writing, on behalf of the constituency that we serve—midlife and older women—to express our viewpoint for consideration by the committee.

The Older Women's League (OWL) is a leading nonprofit independent organization dedicated to the needs of midlife and older women—from health to financial security, from quality of life to women's status in society. OWL conducts research, education, and advocacy activities through an extensive chapter network and is the only national grassroots membership organization to focus solely on issues unique to women as they age.

Several years ago, OWL produced a pamphlet entitled "What Every Woman Should Know: A Special Guide to Nonprescription Medicines for Midlife and Older Women" (a copy is enclosed). The pamphlet is an educational consumer piece that provides tips to women on how to safely use OTC medicines. These products, sold in drug stores, grocery stores, and retail outlets, can help address minor health conditions such as headaches and backaches, or can help ease the symptoms of chronic illnesses, like asthma or arthritis. Often, the purchase of these products becomes the first line of defense against sickness, before making a visit to the physician. OWL wanted to put detailed information into women's hands so that they could make the best decisions on how to use OTC medicines.

Because we believe in the importance of self-care, OWL was pleased to see significant changes in drug product labels this past spring. This important information is now much easier to understand, and allows consumers to quickly see what the ingredients, directions, and warnings are for each product. OWL believes that FDA and industry have already made solid strides in medicine labeling. With better labeling by industry, along with further education campaigns by groups like OWL, we can improve the decision-making process for consumers.

Therefore, we do not believe there is sufficient reason for the committee to limit the variety of approved OTC products on the market. We hope you will continue to keep these products, which so many women use, readily available to consumers.

Sincerely,

Dr. Laurie Young

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